REMARKS

Claims 1-13 are pending in the application, of which claims 1-13 stand rejected.

PROVISIONAL DOUBLE PATENTING REJECTION

Claims 1-13 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/227,161. Since this is only a provisional rejection, no action is required of Applicants in response.

REJECTIONS UNDER 35 U.S.C. 102

Claims 4 and 13 stand rejected under 35 U.S.C. 102(e) as being anticipated by Berish (6,551,317). The Office Action states that with "respect to claims 14 and 13, Berish et al disclose a method of treating a bone defect comprising the steps of applying a reduced pressure to the bone defect; ... and, maintaining the reduced pressure until the bone defect has progressed toward a selected stage of healing, the selected stage of healing including formation of neo-osteoid tissue;..." (Citations omitted.) Applicants respectfully disagree with the rejection for at least the reason that Berish has nothing to do with a method or device relating to reduced pressure treatment. Rather, Berish relates to the opposite – a method and device for treatment with increased (compressive) pressure.

Specifically, Berish relates to a method and apparatus "for treating bone fractures by the application of intermittent pneumatic **compression**." (Berish, Abstract and Field of the Invention. Emphasis Added.) Berish teaches that "[i]ntermittent pneumatic compression is the technique of cyclically **compressing the limb with air pressure**... applied from a source of compressed air by a control mechanism to provide a pulse of pressure that intermittently inflates a cuff enveloping all or part of an arm or leg." (Berish, column 1, lines 19-25. Emphasis Added.) For example, Berish discloses an "apparatus comprising an inflatable cuff capable of being applied to a site at or proximal to the bone fracture, and a pump... being controlled by a timer to **pressurize** the cuff..." (Berish, column 2, lines 62-66. Emphasis Added.) In operation, "the cuff or bladder is inflated to the desired pressure... to partially occlude the venous system to provide venous stasis in the region of the bone fracture.... typically, the level of such

compression will be at least about 30-75% of the baseline compression..." (Berish, column 3, lines 50-55 and column 4 lines 20-22. Emphasis Added.) That is, the inflated cuff provides an increased compressive pressure on the tissue it surrounds with the value of the increased pressure being between about 30% and 75% above the baseline.

In contrast, Applicants' invention relates to applying a *reduced pressure*, and each independent claim recites the feature of "reduced pressure". Reduced pressure is clearly defined in the specification to be "pressure that is below ambient atmospheric pressure." (See paragraph [0006], first sentence.) In this regard, claim 4 recites the steps of "(a) applying a reduced pressure to a bone defect; and (b) maintaining the reduced pressure until new bone tissue has grown at the defect to provide a selected stage of healing." Claim 13 recites the steps of "applying a reduced pressure to the bone defect; and maintaining said reduced pressure until the bone defect has progressed toward a selected stage of healing, the selected stage of healing including formation of neo-osteoid tissue." Application of reduced pressure as disclosed and claimed by Applicants is opposite to the disclosure and teaching of Berish. Berish has nothing to do with application of reduced pressure.

For example, applying compressed air to a site as taught in Berish equates with applying an increased pressure to a site at or proximal to a bone fracture, not a reduced pressure. A source of compressed air, as disclosed in Berish, is one that provides an increased pressure relative to ambient, not a decreased pressure relative to ambient. For example, one well-known source of compressed air is the air pump found at a gas station. A compressed air source is not a source of reduced pressure. Applying compressed air to tissue puts such tissue under compression and not under reduced pressure. Indeed, compressed air and compression are the opposite of reduced pressure and applying reduced pressure.

For at least the above reasons, Berish fails to disclose each and every element recited in independent claims 4 and 13. Therefore, Applicants respectfully request that the rejections of claims 4 and 13 be withdrawn.

REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Berish in view of Argenta (5,636,643). The Office Action states that with respect to claims 1-13, "Berish

et al disclose a method for administering, applying, facilitating, treating and healing a reduced pressure treatment to a damaged bone tissue", with which Applicants strongly disagree for the reasons presented above. The Office Action further states that "it is noted that Berish et al did not teach the steps of providing an impermeable cover adapted to enclose the damaged bone tissue and adapted to maintain reduced pressure at the site of the damaged bone tissue; providing a seal adapted to seal the cover to tissue surrounding the damaged bone tissue; providing reduced pressure supply means for connection to a source of suction, the reduced pressure supply means cooperating with the cover to supply the reduced pressure beneath the cover,...", etc. (See Office Action, page 4.) Applicants respectfully submit that the prior art combination is improper for the following reasons.

First, Applicants respectfully point out as stated above that Berish relates not to a reduced pressure device/method but to an *increased compressive pressure device/method.* Since the present invention is directed to a device/method for applying reduced pressure, Berish is non-analogous art relative to the present invention and therefore is not available for making a rejection under 35 U.S.C. 103. See MPEP 2141.01(a): "While Patent Office classification of references and the cross-references in the official search notes are some evidence of 'nonanalogy' or 'analogy' respectively, the court has found 'the similarities and differences in structure and function of the inventions to carry far greater weight.' *In re Ellis*, 476 F.2d 1370, 1372, 177 USPQ 526, 527 (CCPA 1973). In the instant case, Berish is non-analogous art, because it relates to a device/method for applying increased pressure which is the completely opposite to a device/method for applying reduced pressure as claimed by Applicants.

Second, the purpose of the Berish device/method is to provide increased compressive pressure on a tissue. Berish makes no mention whatsoever of using reduced pressure at a tissue site. **Berish teaches a way from reduced pressure**. Thus, there is no motivation to modify the device/method of Berish to attain reduced pressure as claimed by Applicants.

Third, any proposed modification of Berish to turn it into a reduced pressure device **would render the device/method of Berish inoperable for its intended purpose**. As already explained, the purpose of the Berish device is to provide an increased compressive pressure on tissue. Applying increased compressive pressure is the antithesis of applying reduced pressure to a tissue. It is a well-established principle that it cannot be obvious to modify a reference to

render it inoperable for its intended purpose. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." MPEP 2143.01. Hence, there is no motivation to modify Berish in view of Argenta.

For all the above reasons, Applicants respectfully submit that the proposed prior art combination of Berish with Argenta is improper. Accordingly, Applicants respectfully request that the rejections of claims 1-13 be withdrawn.

In view of the foregoing amendments and remarks, it is believed that the claims in this application are now in condition for allowance. Early and favorable reconsideration is respectfully requested. The Examiner is invited to telephone the undersigned in the event that a telephone interview will advance prosecution of this application.

Respectfully submitted,

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